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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/455,683	05/31/1995	GRAEME I. BELL	ARCD:177/WIM	8952
7590 09/22/2004			EXAMINER	
DAVID L. PARKER FULBRIGHT & JAWORSKI 600 CONGRESS AVENUE SUITE 2400 AUSTIN, TX 78701			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/455,683

Applicant(s)

BELL ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-102, 109, 112-114, 123 and 137-156 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97-102, 109, 112-114, 123 and 137-156 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 6/30/04 has been entered into the record.
- B. Claims 53-58, 60-62, 68-80, 97-102, 109, 112-114, 123, and 137-156 were pending in this application. Claims 53-58, 60-62 and 68-80 have been withdrawn as being drawn to a non-elected invention. Therefore, 97-102, 109, 112-114, 123, and 137-156 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – written description

- A. Claims 97-102, 109, 112-114, 123, and 137-156 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-3 of the Office Action dated 1/28/04. Applicants argue that there is no case law to support the fact that the full-length receptor must be disclosed to fulfill the written description requirement and that, for the purposes of written description, the invention is whatever is actually claimed. They argue that, by providing the sequence of SEQ ID NO:11 and the encoded polypeptide of SEQ ID NO:12, Applicants have indicated that they were in possession of SEQ ID NO:11, which is what the claims recite. They further argue that the Examiner has not disputed the thousands of species within the scope of the claims (i.e. fragments) and that “there is simply no legal precedent or other principle of patent law that an applicant provide one specific species in order to satisfy the written description requirement when the claims do not recite that specific species.”

Applicants argue that the present claims are not reach-through claims since these types of claims are defined by the PTO as “claims to future inventions based on currently disclosed inventions.” Applicants argue that the screening claims in the present case can be practiced with or without the full-length sequence and that there is no requirement for Applicants to disclose every conceivable and possible future embodiment. Finally, Applicants argue that using the full-length receptor in a screening assay is a future embodiment, which is not required to achieve the utility of the invention.

The Examiner’s statement regarding the present claims being “reach-through” claims has been withdrawn in view of the fact that the present claims do not fit the pattern of reach-through” claims. However, the remaining arguments have been considered, but are not deemed persuasive. The Examiner is not questioning the fact that thousands of species of polynucleotide or encoded polypeptide would fall

Art Unit: 1647

under SEQ ID NO:11 or 12, or that Applicants have not disclosed every conceivable and possible future embodiment. The fact remains that Applicants have not disclosed a representative number of species in the genus encompassed by the claims. Therefore, whereas there may not be any legal precedent or other principle of patent law that an applicant provide one specific species in order to satisfy the written description requirement when the claims do not recite that specific species, there is a requirement that Applicants disclose a representative number of species, which they have not done. Therefore, what is actually claimed are methods requiring an entire genus of receptors which are not adequately described. Regarding Applicants' argument that they were in possession of SEQ ID NO:11, which is what the claims recite – the Examiner agrees that Applicants were in possession of SEQ ID NO:11 and that Applicants would be entitled to claims in which the receptor *consists* of SEQ ID NO:11 or 12. However, the claims are not limited to these exact sequences.

It is believed that all pertinent arguments have been addressed.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claims 97-102, 109, 112-114, 123, and 137-156 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' argument that "there is no evidence or argument that a person could not make and use the claimed invention without the full-length sequence." Upon further consideration, the Examiner has concluded that, even in the absence of the full-length receptor, the artisan would know how to make and use the present invention. Even though the claims read on the full-length receptor, which Applicants have not enabled, the fact remains that the screening methods themselves would be enabled regardless of whether or not Applicants have enabled the full-length receptor itself. This is further supported by the wealth of knowledge of the opioid receptor art regarding how to screen for ligands to opioid receptors.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1647

4. Conclusion

A. No claim is allowable.

Advisory information

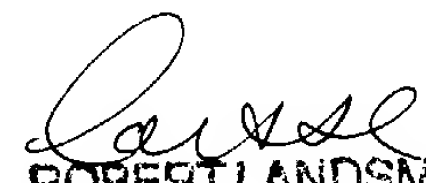
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 20, 2004


ROBERT LANDSMAN
PATENT EXAMINER